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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MEMORANDUM

MAR 1 6 1993

TO:

Richard Mountfort (25)

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Registration Division (TS-767)

THRU:

Orville E. Paynter, Ph.D.

Chief, Toxicology Branch

Hazard Evaluation Division (TS-769)

SUBJECT:

Expansion of Statistical Comparison Presented in Memo

of 8/2/82: Review of Dominant Lethal Test of Thidiazuron

CASWELL#659A

Registrant:

Nor-Am Agricultural Products

350 West Shuman Blvd.

Naperville, Illinois 60566

Background Information:

In the couse of a meeting held on 3/14/83 concerning this study, the question of the statistical comparison of the high dose group to the control group at week one arose. The following discussion expands upon my statistical comparison.

Recommendation/Discussion:

Further examination of the data indicates that statistical significance at the p < .01 level is achieved and my original review therefore need not be changed.

The statistical method used (the chi square) is that recommended by Bateman for use in dominant lethal studies. The formula used is as follows:

$$X_2$$
 (Yates Uncorrected) = $\frac{(0_{11} \cdot 0_{22} \cdot 0_{12} \cdot 0_{21})^{2} \cdot n}{0_{1} \cdot 0_{2} \cdot 0_{12} \cdot 0_{21}}$

As recommended by Remington and Schork 2 , a Yates correction is not used.

The vehicle control group had 23 dead implants out of a total of 587 implants at week 1. The 400 mg/kg high dose group had a total 56 dead implants of 573 total implants at week 1. Thus,

 $x^2 = 15.66$, with one degree of freedom,

p < .0005.

¹Bateman, A.J. "The Dominant Lethal Assay in the Male Mouse" in Handbook of Mutagenicity Test Procedures, Kilbey, Legator, Nichols and Ramel, eds., Elsevier/North Holland Biomedical Press, 1977.

²Remington, R.D. and Schork, M.A. <u>Statistics with Applications to the Biological and Health Sciences</u>, <u>Prentice-Hall Inc.</u>, 1970.

Gary J. Burin, Toxicologist,

Review Section V

Toxicology Branch/HED (TS-769)

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